IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

STEPHEN GRIFFIN and SHELBY GRIFFIN,	:	CIVIL ACTION
Plaintiffs,	:	NO. 02-CV-3282
vs.	:	
BAYER CORPORATION, BAYER AG, GLAXOSMITHKLINE, PLC, GLAXOSMITHKLINE, SMITHKLINE BEECHAM	:	(Pending transfer to *In re Baycol Products Litigation* MDL 1431 (D.Minn.)).
Defendants.	:	

ANSWER AND DEFENSES OF DEFENDANT BAYER CORPORATION

Defendant BAYER CORPORATION ("Bayer") answers the Complaint in this action as follows:

1. The allegations in paragraph 1 of the Complaint set forth legal conclusions to which no response is required. To the extent that a response is required, Bayer is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 1, except that Bayer denies that Plaintiffs are entitled to any relief.

2. Bayer is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 2.

3. Bayer admits that it is a corporation with its principal place of business at 100 Bayer Road, Pittsburgh, PA. Bayer denies the remaining allegations of paragraph 3.

4. Bayer admits that Bayer AG is a German corporation with its principal place of business in Leverkusen, Germany. Bayer denies the remaining allegations in paragraph 4. For a further response, Bayer states that to the extent that the Complaint contains allegations that are directed to Bayer AG by use of the term "defendants" or otherwise, no answer is required by Bayer, and Bayer therefore makes no response in this Answer to the allegations that are directed to Bayer AG.

5. Bayer denies the allegations in paragraph 5.

6. Bayer admits that Bayer Corporation is a wholly owned subsidiary of Bayer AG. Bayer denies the remaining allegations in paragraph 6.

7. Bayer denies the allegations in paragraph 7.

8. Bayer admits, on information and belief, that GlaxoSmithKline plc is an English public limited company with its principal place of business in England. Bayer is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 8.

9. Bayer is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 9.

10. Bayer admits, on information and belief, that SmithKline Beecham Corporation is a Pennsylvania corporation with its principal place of business in Pennsylvania. Bayer is without knowledge and information sufficient to form a belief as to the truth of the remaining allegations in paragraph 10.

11. Bayer is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 11.

12. Bayer admits that cerivastatin sodium, a prescription medication, was sold under the trade name Baycol® in the United States and the trade name Lipobay® in certain countries outside of the United States. Bayer denies the remaining allegations in paragraph 12.

13. Bayer admits that Baycol®, a prescription medication also known as cerivastatin sodium, was manufactured in Germany. Bayer denies the remaining allegations in paragraph 13.

14. Bayer admits that prior to August 8, 2001, Bayer AG manufactured cerivastatin sodium in Germany and Bayer sold Baycol®, also known as cerivastatin sodium, in the United States. Because of the vagueness and ambiguity of the remaining allegations in paragraph 14, Bayer is without knowledge or information sufficient to form a belief as to the truth of such allegations.

15. Bayer is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 15.

16. Bayer denies the allegations in paragraph 16.

17. Because of the vagueness and ambiguity of the allegations in paragraph 17, Bayer is without knowledge or information sufficient to form a belief as to the truth of such allegations.

18. Bayer admits that Plaintiffs purport to commence an action seeking relief, but Bayer denies that Plaintiffs is entitled to any relief. Bayer admits that Baycol® is a prescription medication also known as cerivastatin sodium, and that cerivastatin sodium is known as Lipobay® in certain countries outside of the United States. Bayer denies that Plaintiffs were injured as a result of ingestion of Baycol® as sold by Bayer. Bayer is without knowledge

or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 18.

19. Bayer admits that, prior to August 8, 2001, Bayer promoted and sold Baycol® in the United States, that prior to August 8, 2001, SmithKline Beecham Corporation d/b/a GlaxoSmithKline participated in the promotion of Baycol® in the United States, and that it is estimated that, prior to August 8, 2001, more than 700,000 persons took Baycol® in the United States. Because of the vagueness and ambiguity of the remaining allegations in paragraph 19, Bayer is without knowledge or information sufficient to form a belief as to the truth of such allegations.

20. Bayer denies the allegations in paragraph 20.

21. Bayer denies the allegations in paragraph 21.

22. Bayer denies the allegations in paragraph 22.

23. Bayer denies the allegations in paragraph 23.

24. Bayer admits that, prior to August 8, 2001, it marketed Baycol® in the United States as safe for use in accordance with prescribing information and under the care of a physician or other health care provider. Bayer denies the remaining allegations in paragraph 24.

25. Bayer denies the allegations in paragraph 25.

26. Bayer denies the allegations in paragraph 26.

27. Bayer denies the allegations in paragraph 27.

28. Bayer admits that, prior to August 8, 2001, Bayer promoted, marketed, distributed and sold Baycol®, a prescription medication, in the United States, including in Pennsylvania, and that prior to August 8, 2001, SmithKline Beecham Corporation d/b/a GlaxoSmithKline participated in the promotion of Baycol® in the United States. Bayer admits

that it has promoted, marketed, distributed and/or sold certain prescription and non-prescription drug products in Pennsylvania. Bayer denies that Bayer and SmithKline Beecham d/b/a GlaxoSmithKline manufactured Baycol®. Bayer denies the allegations in paragraph 28 to the extent that they relate to Bayer AG. Because of the vagueness and ambiguity of the remaining allegations in paragraph 28, Bayer is without knowledge or information sufficient to form a belief as to the truth of such allegations.

29. Bayer is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 29.

30. Bayer is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 30.

31. Bayer denies the allegations in paragraph 31.

32. Bayer admits that at least five other statins have been approved by the United States Food and Drug Administration (the "FDA") for sale in the United States, and that statins block the activity of an enzyme that is involved in the production of cholesterol in the liver. Bayer is without knowledge or information sufficient to form a belief regarding the truth of the remaining allegations in paragraph 32.

33. Bayer denies the allegations of paragraph 33.

34. Bayer denies the allegations of paragraph 34.

35. Bayer denies the allegations of paragraph 35.

36. Bayer admits that in June 1997, the FDA approved Bayer's application to market Baycol® in the United States, that prior to August 8, 2001, Bayer marketed Baycol® in the United States, and that prior to August 8, 2001, SmithKline Beecham Corporation d/b/a GlaxoSmithKline participated in the promotion of Baycol® in the United States. Bayer admits

that Bayer voluntarily withdrew Baycol® from the market in the United States on August 8, 2001. Bayer denies the remaining allegations in paragraph 36.

37. Bayer admits that the FDA made an announcement regarding the voluntary withdrawal of Baycol® from the market in the United States. That announcement is in writing and speaks for itself. To the extent that Plaintiffs' allegations regarding the content of that announcement are inconsistent with the actual language of the announcement, Bayer denies those allegations. Because of the vagueness and ambiguity of the remaining allegations in paragraph 37, Bayer is without knowledge or information sufficient to form a belief as to the truth of such allegations.

38. Bayer admits that all statins, including Baycol®, have been associated with reports of rhabdomyolysis, that the symptoms of rhabdomyolysis may include muscle pain, tenderness and weakness, malaise and nausea, and that in severe cases involving persons susceptible to renal injury, rhabdomyolysis may involve renal failure which can be fatal. Because of the vagueness and ambiguity of the remaining allegations in paragraph 38, Bayer is without knowledge or information sufficient to form a belief as to the truth of such allegations.

39. Because of the vagueness and ambiguity of the allegations in paragraph 39, Bayer is without knowledge or information sufficient to form a belief as to the truth of such allegations.

40. Bayer denies the allegations in paragraph 40.

41. Bayer admits that it discontinued sampling of the 0.8 mg dose of Baycol® through its sales representatives in 2001. Bayer denies the remaining allegations in paragraph 41.

42. Paragraph 42 apparently purports to describe the FDA's announcement regarding Bayer's voluntary withdrawal of Baycol® from the market in the United States on August 8, 2001, which announcement is in writing and speaks for itself. To the extent that Plaintiffs' allegations regarding the content of that announcement are inconsistent with the actual language of the announcement, Bayer denies those allegations. Because of the vagueness and ambiguity of the remaining allegations in paragraph 42, Bayer is without knowledge or information sufficient to form a belief as to the truth of such allegations.

43. Bayer admits that Baycol® is one of several drug products generally included within the class of drug products known as statins, which block the activity of an enzyme that is involved in the production of cholesterol in the liver. Bayer also admits that all statins have been associated with reports of rhabdomyolysis. Bayer also admits that rhabdomyolysis is a condition that results from the breakdown of muscle cells and the release of contents of muscle cells into the bloodstream, that the symptoms of rhabdomyolysis may include muscle pain and tenderness, and that in severe cases involving persons susceptible to renal injury, rhabdomyolysis may involve renal failure, which can be fatal. Because of the vagueness and ambiguity in the remaining allegations in paragraph 43, Bayer is without knowledge or information sufficient to form a belief as to the truth of those allegations.

44. Bayer denies the allegations in paragraph 44.

45. Paragraph 45 apparently purports to describe the FDA's announcement regarding Bayer's voluntary withdrawal of Baycol® from the market in the United States on August 8, 2001. The FDA's announcement is in writing and speaks for itself. To the extent that Plaintiffs' allegations regarding the content of that announcement are inconsistent with the actual language of the announcement, Bayer denies those allegations. Bayer admits that the symptoms

of rhabdomyolysis may include muscle pain, tenderness and weakness, malaise, fever, dark urine, nausea and vomiting, that the muscle pain may be diffuse or specific to particular muscle groups, and that in severe cases involving persons susceptible to renal injury, rhabdomyolysis may involve renal failure, which can be fatal. Bayer denies the remaining allegations in paragraph 45.

46. Because of the vagueness and ambiguity of the allegations in paragraph 46, Bayer is without knowledge or information sufficient to form a belief as to the truth of such allegations.

47. Because of the vagueness and ambiguity of the allegations in paragraph 47, Bayer is without knowledge or information sufficient to form a belief as to the truth of such allegations.

48. Bayer denies the allegations in paragraph 48.

49. Bayer denies the allegations in paragraph 49.

50. Bayer denies the allegations in paragraph 50.

51. Bayer denies the allegations in paragraph 51.

52. Bayer denies the allegations in paragraph 52.

53. Bayer denies the allegations in paragraph 53.

54. Bayer denies the allegations in paragraph 54.

55. Bayer denies the allegations in paragraph 55.

56. Bayer denies the allegations in paragraph 56.

57. Bayer denies the allegations in paragraph 57.

58. The February 18, 1998 announcement referred to in paragraph 58 is in writing and speaks for itself. To the extent that Plaintiffs' allegations regarding the content of

that announcement are inconsistent with the actual language of the announcement, Bayer denies those allegations. Because of the vagueness and ambiguity of the remaining allegations in paragraph 58, Bayer is without knowledge or information sufficient to form a belief as to the truth of such allegations.

59. Bayer admits that the FDA approved Bayer's application to market a 0.4 mg dose of Baycol® in the United States in May 1999. Bayer denies the remaining allegations in paragraph 59.

60. Because of the vagueness and ambiguity of the allegations in paragraph 60, Bayer is without knowledge or information sufficient to form a belief as to the truth of such allegations.

61. Bayer admits that paragraph 61 purports to describe an October 25, 1999 letter from Michael A. Misocky of the FDA's Division of Drug Marketing, Advertising and Communications and certain written materials referred to in that letter. Those documents, being in writing, speak for themselves. To the extent that Plaintiffs' allegations regarding the contents of those documents are inconsistent with the actual language of the documents, Bayer denies those allegations. Bayer denies the remaining allegations in paragraph 61.

62. Because of the vagueness and ambiguity of the allegations in paragraph 62, Bayer is without knowledge or information sufficient to form a belief as to the truth of such allegations.

63. Bayer admits that the FDA approved Bayer's application to market a 0.8 mg dose of Baycol® in the United States in July 2000. Bayer denies the remaining allegations in paragraph 63.

64. Bayer admits that it issued a "Dear Health Care Professional" letter in May 2001. That letter, being in writing, speaks for itself. To the extent that Plaintiffs' allegations regarding the content of that letter are inconsistent with the actual language of the letter, Bayer denies those allegations. Bayer denies the remaining allegations in paragraph 64.

65. Bayer admits that paragraph 65 purports to quote portions of a letter dated August 8, 2001 from E. Paul MacCarthy, M.D., Vice President of Bayer, addressed to healthcare professionals. That letter, being in writing, speaks for itself. To the extent that Plaintiffs' allegations regarding the content of that letter are inconsistent with the actual language of the letter, Bayer denies those allegations. Bayer denies the remaining allegations in paragraph 65.

66. Bayer admits that, on August 8, 2001, Bayer voluntarily withdrew Baycol® from the market in the United States. Bayer denies the remaining allegations in paragraph 66.

67. Because Plaintiffs fail to identify the letter referenced in paragraph 67, Bayer is without knowledge or information sufficient to form a belief as to the truth of the allegations in the first sentence in paragraph 67. Bayer denies the remaining allegations in paragraph 67.

68. Bayer denies the allegations in paragraph 68.

69. Bayer denies the allegations in paragraph 69.

70. Bayer denies the allegations in paragraph 70.

71. Bayer admits that, prior to August 8, 2001, SmithKline Beecham Corporation d/b/a GlaxoSmithKline participated in the promotion of Baycol® in the United States. Because of the vagueness and ambiguity of the remaining allegations in paragraph 71,

Bayer is without knowledge or information sufficient to form a belief as to the truth of such allegations.

72. Bayer admits that, prior to August 8, 2001, Bayer promoted, marketed and distributed Baycol® in the United States. Because of the vagueness and ambiguity of the remaining allegations in paragraph 72, Bayer is without knowledge or information sufficient to form a belief as to the truth of such allegations.

73. Bayer is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 73.

74. Bayer is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 74.

75. In response to the allegations in paragraph 75, Bayer incorporates by reference its responses to paragraphs 1 through 74 of the Complaint.

76. Bayer denies the allegations in paragraph 76.

77. Paragraph 77 sets forth conclusions of law to which no response is required. To the extent that a response is required, Bayer denies the allegations of paragraph 77.

78. Paragraph 78 sets forth conclusions of law to which no response is required. To the extent that a response is required, Bayer denies the allegations of paragraph 78.

79. Paragraph 79 sets forth conclusions of law to which no response is required. To the extent that a response is required, Bayer denies the allegations of paragraph 79.

COUNT I

80. In response to the allegations in paragraph 80, Bayer incorporates by reference its responses to paragraphs 1 through 79 of the Complaint.

81. Bayer denies the allegations in paragraph 81.

82. Bayer denies the allegations in paragraph 82.

83. Bayer denies the allegations in paragraph 83.

84. Bayer denies the allegations in paragraph 84, including subparts (a) through (i).

85. Bayer denies the allegations in paragraph 85.

COUNT II

86. In response to the allegations in the first sentence of paragraph 86, Bayer incorporates by reference its responses to paragraphs 1 through 85 of the Complaint. Bayer denies the remaining allegations of paragraph 86.

87. Bayer denies the allegations in paragraph 87, including subparts (a) through (l).

88. Bayer denies the allegations in paragraph 88.

89. Bayer denies the allegations in paragraph 89.

90. Bayer denies the allegations in paragraph 90.

91. Bayer denies the allegations in paragraph 91.

92. Bayer denies the allegations in paragraph 92.

COUNT III

93. In response to the allegations in paragraph 93, Bayer incorporates by reference its responses to paragraphs 1 through 92 of the Complaint.

94. Bayer admits that, prior to August 8, 2001, Bayer marketed, promoted, distributed and sold Baycol® in the United States. Bayer also admits that, prior to August 8, 2001, Bayer AG manufactured and sold cerivastatin sodium. Bayer further admits that, prior to August 8, 2001, SmithKline Beecham Corporation d/b/a GlaxoSmithKline participated in the

promotion of Baycol® in the United States. Bayer denies that Bayer, GlaxoSmithKline, GlaxoSmithKline plc and SmithKline Beecham Corporation manufactured Baycol®. Because of the vagueness and ambiguity of the remaining allegations in the first sentence in paragraph 94, Bayer is without knowledge or information sufficient to form a belief as to the truth of such allegations. Bayer denies the remaining allegations in paragraph 94, including subparts (a) through (g).

95. Bayer denies the allegations in paragraph 95.

96. Bayer denies the allegations in paragraph 96.

97. Bayer denies the allegations in paragraph 97.

98. Paragraph 98 sets forth conclusions of law to which no response is required. To the extent that a response is required, Bayer admits that, prior to August 8, 2001, Bayer sold Baycol® in the United States, and that, prior to August 8, 2001, Bayer AG manufactured cerivastatin sodium. Bayer denies that it violated any duty relating to Baycol® or the manufacture and/or sale of Baycol®, as alleged in the Complaint. Because of the vagueness and ambiguity of the remaining allegations in paragraph 98, Bayer is without knowledge or information sufficient to form a belief as to the truth of such allegations, including the allegation that Bayer had any duty to Plaintiffs.

99. Because of the vagueness and ambiguity of the allegations of paragraph 99, Bayer is without knowledge or information sufficient to form a belief as to the truth of such allegations.

100. Paragraph 100 sets forth conclusions of law to which no response is required. To the extent that a response is required, Bayer denies that it violated any duty relating to Baycol®, as alleged in the Complaint. Because of the vagueness and ambiguity of the

remaining allegations in paragraph 100, Bayer is without knowledge or information sufficient to form a belief as to the truth of such allegations, including any allegation that Bayer had any duty to Plaintiffs.

101. Bayer denies the allegations of paragraph 101, including subparts (a) through (d).

102. Bayer denies the allegations of paragraph 102.

COUNT IV

103. In response to the allegations in paragraph 103, Bayer incorporates by reference its responses to paragraphs 1 through 102 of the Complaint.

104. Bayer denies the allegations of paragraph 104.

105. Bayer denies the allegations of paragraph 105.

106. Bayer denies the allegations of paragraph 106.

107. Bayer denies the allegations of paragraph 107.

COUNT V

108. In response to the allegations in paragraph 108, Bayer incorporates by reference its responses to paragraphs 1 through 107 of the Complaint.

109. Paragraph 109 sets forth conclusions of law to which no response is required. To the extent that a response is required, Bayer admits that Baycol® was intended to be used to lower elevated plasma levels of total and low-density lipoprotein cholesterol and triglycerides, and to increase plasma levels of high-density lipoprotein cholesterol, in patients, and that, prior to August 8, 2001, Bayer marketed, sold, distributed and promoted Baycol® in the United States as safe for such use, according to prescribing information and under the care of a

physician or other health care provider. Bayer denies the remaining allegations of paragraph 109.

110. Bayer denies the allegations of paragraph 110.

111. Bayer denies the allegations of paragraph 111.

112. Bayer denies the allegations of paragraph 112.

113. Bayer denies the allegations of paragraph 113.

COUNT VI

114. In response to the allegations in paragraph 114, Bayer incorporates by reference its responses to paragraphs 1 through 113 of the Complaint.

115. Paragraph 115 sets forth conclusions of law to which no response is required. To the extent that a response is required, Bayer admits that, prior to August 8, 2001, it marketed Baycol® in the United States as safe for use in accordance with prescribing information and under the care of a physician or other health care provider. Bayer denies the remaining allegations of paragraph 115.

116. Bayer denies the allegations of paragraph 116.

COUNT VII

117. In response to the allegations in paragraph 117, Bayer incorporates by reference its responses to paragraphs 1 through 116 of the Complaint.

118. Paragraph 118 sets forth conclusions of law to which no response is required. To the extent that a response is required, Bayer denies that it violated any law relating to Baycol®. Because of the vagueness and ambiguity of the remaining allegations in paragraph 118 Bayer is without knowledge or information sufficient to form a belief as to the truth of such allegations, including any allegation that Bayer had any obligation to Plaintiffs.

119. Paragraph 119 sets forth conclusions of law to which no response is required. To the extent that a response is required, Bayer denies the allegations of paragraph 119.

120. Bayer denies the allegations of paragraph 120.

121. Bayer denies the allegations of paragraph 121.

122. Bayer denies the allegations of paragraph 122.

COUNT VIII

123. In response to the allegations in paragraph 123, Bayer incorporates by reference its responses to paragraphs 1 through 122 of the Complaint.

124. Bayer is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 124.

125. Bayer is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 125.

126. Bayer denies the allegations of paragraph 126.

COUNT IX

127. In response to the allegations in paragraph 127, Bayer incorporates by reference its responses to paragraphs 1 through 126 of the Complaint.

128. Bayer denies the allegations of paragraph 128.

129. Bayer denies the allegations of paragraph 129.

130. Bayer denies the allegations in the Prayer for Relief. Bayer denies that Plaintiffs are entitled to any relief whatsoever.

131. Bayer denies all allegations in the Complaint that relate or are directed to Bayer unless those allegations are expressly admitted in this Answer.

ADDITIONAL DEFENSES

1. Plaintiffs' Complaint, and each and every count contained therein, fails to state a cause of action or claim upon which relief can be granted against Bayer.

2. Some or all of Plaintiffs' claims are barred by the applicable statutes of limitations and/or statutes of repose.

3. Plaintiffs' claims against Bayer are barred, in whole or in part, by laches, waiver and/or estoppel.

4. Plaintiffs' claims are barred, in whole or in part, by Plaintiffs' failure to mitigate alleged damages.

5. If Plaintiffs sustained the injuries or incurred the expenses as alleged, which is expressly denied, said injuries or expenses were directly and proximately caused by the negligence or fault of parties other than Bayer, whether named or unnamed in Plaintiffs' Complaint, over whom Bayer had no supervision or control and for whose actions and omissions Bayer has no legal responsibility. Plaintiffs' recovery, if any, therefore should be apportioned in accordance with the applicable law.

6. The injuries and damages claimed by Plaintiffs, if any, resulted from an intervening or superseding cause and/or causes, and any act or omission on the part of Bayer was not the proximate and/or competent producing cause of such alleged injuries and damages.

7. If Plaintiffs suffered injuries as alleged in the Complaint, which is expressly denied, such injuries arose from, and were caused by, risks, hazards, and dangers knowingly assumed by Plaintiffs. Plaintiffs' recovery accordingly is barred or should be reduced by Plaintiffs' assumption of the risk.

8. Baycol® is a prescription pharmaceutical which was available only upon the prescription of a licensed physician, and persons other than Bayer, including Plaintiffs' treating physicians and health care personnel and institutions, stood in the position of learned intermediary between Bayer and Plaintiffs. The claims in the Complaint against Bayer accordingly are barred in whole or in part by the learned intermediary doctrine.

9. Plaintiffs' recovery is barred and/or should be reduced under the applicable law because of Plaintiffs' contributory negligence and/or contributory fault.

10. Plaintiffs' Complaint fails to state a claim upon which relief can be granted against Bayer in that the methods, standards, and techniques utilized with respect to the design, manufacture, marketing and sale of the prescription drug Baycol®, including adequate warnings and instructions with respect to the product's use included in the product's package insert and other literature, conformed to the applicable state of the art, and the product was designed, manufactured, marketed and sold in a reasonable and prudent manner based upon available medical and scientific knowledge.

11. Plaintiffs' claims are barred as a matter of law pursuant to Restatement (Second) of Torts § 402A, comment k.

12. The prescription drug Baycol® complied with the applicable product safety regulations promulgated by the FDA. Compliance with such regulations demonstrates that due care was exercised with respect to the design, manufacture, testing, marketing and sale of this prescription drug, and that it was neither defective nor unreasonably dangerous.

13. Plaintiffs' claims are preempted, in whole or in part, by federal law pursuant to the Supremacy Clause of the United States Constitution because of the federal regulation of prescription drug manufacturing, testing, marketing, and labeling.

14. If Plaintiffs sustained the injuries or incurred the expenses as alleged, which is expressly denied, said injuries or expenses were caused by the unforeseeable alteration, improper handling, or other unforeseeable misuse of the prescription drug Baycol®.

15. Any claims by Plaintiffs relating to alleged communications with regulatory agencies of the United States government are barred in whole or in part by operation of applicable law, including First Amendment rights to petition the government.

16. The alleged injuries and damages, if any, were the result of unavoidable circumstances that could not have been prevented by any person, including Bayer.

17. Plaintiffs' Complaint fails to state a claim against Bayer upon which relief can be granted for several or joint and several liability.

18. Plaintiffs' Complaint fails to join indispensable parties necessary for the just adjudication of this matter.

19. Plaintiffs' Complaint fails to state a claim against Bayer upon which relief can be granted as to costs, attorneys' fees, pre-judgment interest and post-judgment interest.

20. Plaintiffs' claims are barred in whole or in part because the commercial speech relating to Baycol® was not false or misleading and is protected under the First Amendment of the United States Constitution and the applicable state constitution.

21. Plaintiffs' claims regarding warnings and labeling are barred in whole or in part by the doctrine of primary jurisdiction, in that the FDA is charged under law with determining the content of warnings and labeling for prescription drugs.

22. Plaintiffs cannot state a claim with regard to warnings and labeling for prescription drugs because the remedy sought by Plaintiffs is subject to the exclusive regulation of the FDA.

23. This court should abstain from adjudicating Plaintiffs' claims relating to warnings and labeling in deference to the interpretation of regulations relating to prescription drug labeling by the FDA.

24. Upon information and belief, each item of economic loss alleged in the Complaint was, or with reasonable certainty will be, replaced or indemnified in whole or in part by collateral sources.

25. Plaintiffs did not detrimentally rely on any labeling, warnings or information concerning Baycol®.

26. Plaintiffs' alleged injuries and damages, if any, were the result of an idiosyncratic reaction which Bayer could not reasonably foresee.

27. Plaintiffs' claims for breach of warranty are barred because Plaintiffs failed to give timely notice of any alleged breach of warranty.

28. Bayer did not sell or distribute the prescription drug Baycol® directly to Plaintiffs, and Plaintiffs did not receive or rely upon any representations or warranties as alleged in the Complaint. Plaintiffs' claims are barred by lack of privity between Plaintiffs and Bayer.

29. Plaintiffs' claims for breach of warranty, express or implied, are barred by the applicable provisions of the Uniform Commercial Code.

30. Plaintiffs' Complaint fails to state a claim upon which relief can be granted under the Magnuson-Moss Act.

31. Plaintiffs' purported allegations of fraud, deceit, misrepresentation and concealment do not comply with Rule 9(b) of the Federal Rules of Civil Procedure.

32. Plaintiffs' Complaint fails to state a claim for fraud, deceit, misrepresentation and/or concealment.

33. Plaintiffs' Complaint fails to state a claim against Bayer upon which relief can be granted for punitive or exemplary damages.

34. Plaintiffs' claims for punitive or exemplary damages are barred under the applicable state and federal law. Permitting recovery of punitive or exemplary damages in this case would contravene Bayer's constitutional rights as reserved by the Fifth, Seventh, Eighth, and Fourteenth Amendments to the United States Constitution and other provisions of the United States Constitution and the applicable state constitution.

35. Because of the lack of clear standards, the imposition of punitive or exemplary damages against Bayer would be unconstitutionally vague and/or overbroad.

36. With respect to Plaintiffs' demand for punitive or exemplary damages, Bayer specifically incorporates by reference any and all standards or limitations regarding the determination and enforceability of punitive or exemplary damages awards under the applicable state law.

37. No act or omission of Bayer was malicious, willful, wanton, outrageous, or done with actual malice or done with bad motive and/or with a reckless indifference to the interests of others, and Plaintiffs' Complaint fails to state a claim upon which relief can be granted for punitive or exemplary damages. Plaintiffs' Complaint seeks damages in excess of those permitted by law. Bayer asserts any statutory or judicial protection from punitive or exemplary damages that is available under the applicable law, and any award of punitive or exemplary damages is barred.

38. Plaintiffs' claims asserted under the United States Food Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq., and other statutes and regulations, fail because those statutes and regulations do not contain or create any private cause of action.

39. Plaintiffs' Complaint fails to state a claim upon which relief can be granted for negligence per se.

40. Under applicable state law, there exist no post-sale duties, including a post-sale duty to warn, in the present circumstances. Accordingly, Plaintiffs' Complaint fails to state a claim against Bayer upon which relief can be granted for alleged breach of post-sale duties, including allegedly inadequate post-sale marketing or alleged post-sale duty to warn.

41. Plaintiffs' claims may be barred in whole or in part by release.

42. Venue is improper.

43. This Court is not the proper forum and is not a convenient forum for the adjudication of plaintiffs' claims.

44. Bayer adopts and incorporates by reference all defenses pleaded by other defendants except to the extent that they are inconsistent with Bayer's defenses pleaded in this Answer.

45. Bayer reserves the right to amend its answer and separate and additional defenses to conform to such facts as may be revealed in discovery or otherwise.

WHEREFORE, Bayer prays that judgment be entered in its favor and against Plaintiffs, and that it be awarded costs and such other and further relief as the Court deems just and appropriate.

JURY TRIAL DEMAND

Bayer demands a trial by jury on all issues so triable.

ECKERT SEAMANS CHERIN & MELLOTT, LLC

Dated: August 2, 2002

By_____
ALBERT G. BIXLER
CHARLES F. FORER
LESLIE A. HAYES
Attorneys for defendant Bayer Corporation
1515 Market Street, 9th Floor
Philadelphia, PA 19102-1909
215/851-8400

Of Counsel:

Philip S. Beck
Adam L. Hoeflich
Andrew Goldman
Tarek Ismail
Bartlit Beck Herman Palenchar & Scott
54 West Hubbard Street, Suite 300
Chicago, IL 60610
312/494-4000

Douglas R. Marvin
William R. Murray, Jr.
Allen P. Waxman
Williams & Connolly LLP
725 Twelfth Street, N.W.
Washington, DC 20005-5901
202/434-5000

Sara J. Gourley
Susan A. Weber
Sidley Austin Brown & Wood
Bank One Plaza
10 South Dearborn Street
Chicago, IL 60603
312/853-7000

Richard K. Dandrea
Michael R. Borasky
Eckert Seamans Cherin & Mellott, LLC
600 Grant Street, 44th Floor
Pittsburgh, PA 15219
412/566-6000

CERTIFICATE OF SERVICE

I hereby certify that on this 2nd day of August, 2002, the foregoing Answer and Defenses of Defendant Bayer Corporation was served by U.S. first class mail upon the following counsel of record:

Jerry Kristal, Esquire
Franklin P. Solomon, Esquire
Weitz & Luxenberg, P.C.
51 Haddonfield Road, Suite 160
Cherry Hill, NJ 08002

Hope S. Freiwald, Esquire
Dechert
4000 Bell Atlantic Tower
1717 Arch Street
Philadelphia, PA 19103-2793

_____
Albert G. Bixler, Esquire

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